

## REMARKS

This Amendment is submitted in reply to the Non-Final Office Action mailed on September 24, 2009. The Commissioner is hereby authorized to any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712161-00076 on the account statement.

Claims 12-28 are pending in this application. Claims 12-16 were previously withdrawn and Claims 1-11 and 21-22 were previously canceled without prejudice or disclaimer. Claims 18, 20 and 25-27 are allowed. In the Office Action, Claims 17, 19, 23, 24 and 28 are rejected under 35 U.S.C. §102. In response, Applicants have amended Claims 17, 19, 23 and 28 and canceled Claim 24. The amendments do not add new matter. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully request that the rejections be reconsidered and withdrawn.

Initially, Applicants note that the Patent Office has found Claims 18, 20 and 25-27 to be free of art and, as such, has allowed Claims 18, 20 and 25-27. See, Office Action, page 1 (Office Action Summary) and page 4, lines 1-2.

In the Office Action, Claims 17, 19, 23, 24 and 28 are rejected under 35 U.S.C. §102(b) as being anticipated by Clinical and Experimental Immunology 104, 543-546 (June 1996) to D'Ostillo et al. ("*D'Ostillo*"). For at least the reasons provided below, Applicants respectfully submit that *D'Ostillo* fails to disclose or suggest each and every element of the presently amended claims.

*D'Ostillo* fails to disclose or suggest a food material comprising an osteoprotegerin isolated from human or bovine milk or colostrum, wherein said food material is selected from the group consisting of yogurt, curd, cheese, fermented milks, milk-based fermented products, ice-creams, fermented cereal-based products, milk-based powders, infant formulae and pet food as required, in part, by amended independent Claim 17.

*D'Ostillo* fails to disclose or suggest a food material, enteral composition or pharmaceutical composition comprising osteoprotegerin obtained from recombination methods in cells yielding a glycosylation pattern as found in the milk-OPG, wherein the food material, enteral composition or pharmaceutical composition is selected from the group consisting of yogurt, curd, cheese, fermented milks, milk-based fermented products, ice-creams, fermented

cereal-based products, milk-based powders, infant formulae, pet food, solutions, dried oral supplement, liquid oral supplement, dry tube-feeding and liquid tube-feeding as required, in part, by amended independent Claim 19.

*D'Ostillo* fails to disclose or suggest an enteral composition or a pharmaceutical composition comprising osteoprotegerin isolated from human or bovine milk or colostrums, wherein the enteral composition or pharmaceutical composition is selected from the group consisting of solutions, dried oral supplement, liquid oral supplement, dry tube-feeding and liquid tube-feeding as required, in part, by amended independent Claim 23.

*D'Ostillo* fails to disclose or suggest an ingestible product made by a method of making a food material, enteral composition or pharmaceutical composition, the method comprising adding to the food material, enteral composition or pharmaceutical composition of osteoprotegerin isolated from human or bovine milk or colostrums, wherein the food material, enteral composition or pharmaceutical composition is selected from the group consisting of yogurt, curd, cheese, fermented milks, milk-based fermented products, ice-creams, fermented cereal-based products, milk-based powders, infant formulae, pet food, solutions, dried oral supplement, liquid oral supplement, dry tube-feeding and liquid tube-feeding as required, in part, by amended independent Claim 28. The amendments to Claims 17, 19, 23 and 28 are supported in Applicants' specification (see, US 2004/0137074), for example, at paragraph [0028].

*D'Ostillo* is entirely directed to the isolation of human 90K, also known as Mac-2 binding protein (Mac-2 BP), from human breast milk. See, *D'Ostillo*, page 543, Summary. Human 90K is titled as such because it is a widely expressed, secreted, 90kDa glycoprotein found both in normal healthy individuals and at elevated levels in the serum of cancer patients as well as those suffering from other non-malignant diseases such as HIV. See, *D'Ostillo*, page 543, column 1, lines 15-21. Because human 90K may also provide immune stimulation effects and because human breast milk provides anti-infective and immunomodulatory effects, *D'Ostillo* focuses its study on the isolating and detecting the concentration of human 90K in human breast milk. See, *D'Ostillo*, page 543, column 2, lines 7-14.

Instead of teaching the use of isolated osteoprotegerin in a food material or composition as claimed, *D'Ostillo* is clearly concerned with determining the presence of human 90K that is

naturally occurring in human breast milk. Therefore, *D'Ostillo* fails to disclose or suggest even the use of osteoprotegerin.

Beside failing to even suggest using or isolating osteoprotegerin, *D'Ostillo* fails to disclose or suggest an osteoprotegerin isolated from a human or bovine milk or colostrums, which is included in the food material of amended Claim 17, the food material, enteral composition or pharmaceutical composition of amended Claims 19 or 28, and the enteral composition or pharmaceutical composition of amended Claim 23. Specifically, *D'Ostillo* fails to disclose or suggest isolated osteoprotegerin included in a food material selected from the group consisting of yogurt, curd, cheese, fermented milks, milk-based fermented products, ice-creams, fermented cereal-based products, milk-based powders, infant formulae and pet food, or an enteral composition or pharmaceutical composition selected from the group consisting of solutions, dried oral supplement, liquid oral supplement, dry tube-feeding and liquid tube-feeding. Instead of teaching any of the above food materials, enteral compositions or pharmaceutical compositions, *D'Ostillo* solely teaches the isolation of components of human breast milk.

The Office Action asserts, however, that since the pending claims are product-by-process claims, the claims read as a food material containing osteoprotegerin with a glycosylation pattern giving rise to a molecular weight of approximately 130kDa. See, Office Action, page 3, lines 10-14. The Office Action further asserts that since *D'Ostillo* teaches obtaining human breast milk samples, which is the same source for naturally occurring osteoprotegerin as the instant application, the milk in *D'Ostillo* would inherently have the same osteoprotegerin as the present claims. See, Office Action, page 3, lines 15-22. Applicants submit that the above assertions are moot for at least the reasons provided below.

As stated above, *D'Ostillo* does not disclose or even suggest the use or isolation of osteoprotegerin from human breast milk. In fact, *D'Ostillo* does not mention the presence of osteoprotegerin in human breast milk or, for that matter, osteoprotegerin at all. Moreover, Applicants' specification states that in the studies leading to the present invention, it was surprisingly found that in addition to its presence in e.g. the bone tissues, osteoprotegerin may also be found in human breast milk. In consequence, during breast feeding the mother is obviously supplying the newborn with this bioactive substance in a form that is capable of

surviving in the child's gastro-intestinal tract. From this it follows that the osteoprotegerin produced by mammary gland cells obviously differs from osteoprotegerin isolated from other sources as regards its stability and/or resistance to degradation. See, Applicants' specification, paragraph [0025].

Moreover, regardless of any inherent disclosure of osteoprotegerin in human breast milk, as asserted in the Office Action, the cited references still do not disclose or suggest incorporation of osteoprotegerin into the food material, enteral composition or pharmaceutical composition recited in the presently amended independent claims.

By providing osteoprotegerin ("OPG") as a separate component in the claimed materials or compositions, Applicants can provide products with varied amounts of OPG as needed to control intake and provide enlarged levels where needed. For example, for treating severe cases of osteopenia or osteoporosis, respectively, the preferred regimen may be a pharmaceutical composition, which contains the OPG according to the present invention in higher amounts, that is, in amounts sufficient to stop or even revert the disease process. Such compositions may contain the OPG of the present invention as the only active substance. This has the advantage that no major formulation of the substance has to be envisaged. See, Applicants' specification, paragraph [0035]. Moreover, since OPG have been found in mother's milk, milk-based products such as powders, fermented milks or fermented products, for example, are well-suited as carriers for delivering the isolated OPG to an individual. See, Applicants' specification, paragraph [0034].

It is, therefore, well within the present invention to simply press a tablet consisting of "OPG-powder" optionally supplemented with carriers or flavoring agents. However, in the case that the OPG of the present invention shall be formulated together with other active substances, the nature and liability to degradation of these additional substances in the gastro-intestinal tract shall be considered. The OPG of the present invention, formulated in dosage units, will enable the attending physician to more carefully control the daily or weekly dose of the active compound. See, Applicants' specification, paragraph [0035].

In summary, *D'Ostillo* fails to disclose or suggest the use or isolation of OPG in its discussion of human 90K isolation in human breast milk. Moreover, the present claims recite the OPG as a component of a food material, enteral composition or pharmaceutical composition,

while *D'Ostillo* simply discloses the manipulation of human breast milk. Therefore, besides failing to disclose or suggest isolated OPG as a separate component of a food material or composition, *D'Ostillo* further fails to disclose any of the claimed food materials, enteral compositions or pharmaceutical compositions as a carrier for the isolated OPG.

Applicants respectfully submit therefore that *D'Ostillo* is deficient with respect to the present claims. Accordingly, Applicants respectfully request that the rejection of Claims 17, 19, 23, 24 and 28 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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